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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,685	07/18/2005	Larry I. Benowitz	701039-52287	4644

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EXAMINER	
KRISHNAN, GANAPATHY	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
06/25/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/528,685	BENOWITZ, LARRY I.	
	Examiner	Art Unit	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-11,15-17 and 20-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-11,15-17,20-30,32 and 33* is/are rejected.

7)☒ Claim(s) *31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 3/7/2008 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 2, 6, 12-14 and 18-19 have been canceled.

2. New Claims 27-33 have been added.

3. Claims 1, 4-5, 7, 9-11, 15 and 22 have been amended.

4. Remarks drawn to objection and rejections under 35 USC 112 first and second paragraphs, double patenting and 102.

Claims 1, 3-5, 7-11, 15-17 and 20-33 are pending in the case.

Specification

The objection to the abstract of the disclosure has been overcome by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 1, 3-5, 7-11, 15-17, 27-30 and 32-33 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the regeneration of axons on retinal ganglion cells by administration of mannose and forskolin and a composition comprising mannose and a pharmaceutically acceptable

carrier, does not reasonably provide enablement for the treatment of any neurological disorder as broadly claimed in instant claims is being maintained for reasons of record.

Applicants have traversed the rejection by arguing that:

The regeneration assay example provided by the applicants is an accepted in vitro model and one of ordinary skill in the art would be able to perform the invention through no more than routine experimentation. The artisan would also be aware of that addition of exogenous cAMP modulator is not a requirement in all circumstances. Applicants claim as amended are enabled.

Applicants' arguments have been considered but are not found to be persuasive.

Applicants have not provided a substantive argument. Instant claim 1 as amended still recites neurological disorder. This is a broad term that is seen to include several disorders and enablement is not seen for treating all such disorders with just D-mannose. The regeneration assay example provided is not representative of such treatment. Instant claims 10 and 28 recite terms such as injury, damage and retinopathy, which are all broad terms not defined by the claims. The dictionary defines retinopathy as any noninflammatory disease and fibroplasia is abnormal growth of fibrous tissue. There is no data seen that supports the treatment of such conditions by neuronal outgrowth using just a single active agent.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 4-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention has been overcome by amendments. Thus, the rejection is withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5, 7-11, 15-17 and 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-32 and 34-37 of copending Application No. 10/580364 ('364) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that the claims of '364 are limited to require an NgR antagonist and an agent that activates the growth of CNS neurons and this does not make the instant claims obvious. Applicants' arguments are found to be persuasive. Both the instant claims and the claims of the '364 recite the open ended

language 'comprising'. D-Mannose, which is a hexose, is the known member. The term comprising can include an agent other than the hexose. The rejection is being maintained.

Applicants have also argued that the copending '364 application has a later priority date than the instant and hence does not require a terminal disclaimer.

Effective June 8, 1995, any continuing application of a previously filed application will expire twenty years from the filing date of the earlier case. A terminal disclaimer is still required to overcome a nonstatutory double patenting rejection in a continuing application, even though both patents would expire on the same day anyway because of the twenty-year term provisions under GATT/NAFTA. The reason is that the enforceability/common ownership provision of a terminal disclaimer under 37 CFR 1.321 (C)(3) remains. A terminal disclaimer includes a provision that the later filed application which matures into a patent shall only be enforceable as long as the earlier and later filed patents are commonly owned. If and when the patents cease to be commonly owned, the patent containing the terminal disclaimer does not expire, but it becomes unenforceable. This would avoid the problem of an alleged infringer being harassed by two different parties with patents covering the same patentable invention (as defined in 37 CFR 1.601(n)).

A terminal disclaimer is additionally required because the enforceability/common ownership provision that the later filed application which matures into a patent shall only be enforceable as long as the earlier and later filed patents are commonly owned. If and when the patents cease to be commonly owned, the patent containing the terminal disclaimer does not expire, but it becomes unenforceable. This would avoid the problem

of an alleged infringer being harassed by two different parties with patents covering the same patentable invention (as defined in 37 CFR 1.601(n)).

The rejection of Claims 22-26 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-20 and 22 of copending Application No. 11/804,295 ('295) is being maintained for reasons of record.

Applicants have requested that the rejection be held in abeyance till an indication of allowable subject matter. The rejection will be maintained till an appropriate action to overcome the rejection is filed by the applicants.

The rejection of Claims 1-6, 10, 15-17, 21-22 and 28-33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-10 and 12-13 of U.S. Patent No. 6,855,690 ('690) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that the claims of the '690 patent are limited to require oncomodulin. Mannose is not taught or suggested in the '690 patent. This is not found to be persuasive.

Both the instant claims and the claims of the '690 patent recite the open ended language, 'comprising'. This means that in addition to the active agent that is recited in both the claims there can be other agents present. The '690 patent is not limited to only oncomodulin because of open ended language.

The rejection of Claims 22-26 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 7,238,529 ('529) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that the claims of '529 are limited to require oncomodulin with an axogenic factor such as mannose. The instant claims have no such limitation. This is not found to be persuasive. Both the instant claims and the claims of the '529 patent recite the open ended language 'comprising'. D-Mannose, which is a hexose and oncomodulin are the known members and are recited in both the claims. The term comprising can include other agents too. The rejection is being maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Sherman et al (US 4,471,114) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that claim 22 has been amended to recite that the composition is for treating a neurological disorder of the eye. Sherman does not teach an article of manufacture comprising a packaging material and a label which indicates that the agent contained therein is for treating a neurological disorder of the eye and hence does not anticipate the instant claim. This is not found to be persuasive.

The claim is mainly drawn to composition comprising D-mannose with an acceptable carrier. This combination is taught by Sherman. The recitation regarding what the composition is for is intended use and is not accorded patentable weight. Any pharmaceutical composition is provided with a packaging and a label. This is well known to one of skill in the art and is also well within the skill level of the artisan to put the composition in a packaging and include a label. The art is not required to teach what is well known and common practice.

Conclusion

1. Claims 1, 3-5, 7-11, 15-17 and 20-30 and 32-33 are rejected.
2. Claim 31, drawn to a method wherein contact with mannose of the injured neuron to promote neuronal outgrowth, is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623

GK